

[Federal Register: October 21, 1994]

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DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 171

[Docket No. **HM-181G**; Notice No. 94-10]
RIN 2137-AC36

Infectious Substances; Confirmation of Effective Date and
Compliance Dates

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule; confirmation of effective date and compliance
dates.

SUMMARY: On September 22, 1994, RSPA published a final rule to extend the compliance dates for classification, hazard communication, and packaging requirements of the Hazardous Materials Regulations applicable to infectious substances, including regulated medical waste. The effective date of the rule was September 22, 1994, unless RSPA received, by September 30, 1994, any comments illustrating that an extension of the compliance dates is not in the public interest. RSPA received two comments opposing the extension, but containing no specific information to support that an extension of the compliance dates is not in the public interest. Therefore, this document confirms that the compliance dates are extended as set forth in the September 22, 1994 final rule, and the effective date of that final rule is September 22, 1994.

EFFECTIVE DATE: September 22, 1994.

FOR FURTHER INFORMATION CONTACT: Eileen Martin or Jennifer Antonielli, Office of Hazardous Materials Standards, Research and Special Programs Administration, 400 Seventh St., SW., Washington, DC 20590-0001, telephone: (202) 366-8553.

SUPPLEMENTARY INFORMATION: On September 22, 1994, RSPA issued a final rule under Docket **HM-181G** (59 FR 48762) to extend the compliance dates for classification, hazard communication, and packaging requirements for infectious substances, including regulated medical waste (RMW). In the final rule, RSPA amended 49 CFR 171.14(b) to extend the compliance date from October 1, 1994, to October 1, 1995, for regulatory requirements applicable to RMW and materials infectious to animals only. This extension was provided to allow RSPA sufficient time to publish a Notice of Proposed Rulemaking (NPRM), evaluate comments received in response to the NPRM, and make any necessary changes to the HMR based on the merits of those comments. RSPA stated that, without an extension of the compliance date, shippers and transporters of these materials would have to comply with regulations that are likely to be changed in the near future and thereby incur unnecessary costs. For other infectious substances, i.e., for cultures and stocks of substances infectious to humans, the September 22, 1994 final rule extended the compliance date from October 1, 1994, to January 1, 1995.

The requirements for these materials generally have not been at issue in comments or petitions filed with RSPA. The principal impacts of the January 1, 1995 compliance date will be a nomenclature change from the old ``etiologic agent'' hazard class to the new ``Division 6.2'' classification, elimination of the 50 milliliter exception for cultures and stocks of infectious substances, and expansion of the definition of infectious substances to cover substances, such as the human immunodeficiency virus (HIV) and Lyme disease, which are not listed in the Centers for Disease Control regulations (42 CFR 72.3).

In the preamble of the September 22, 1994 rule, RSPA stated that the compliance dates would be extended unless RSPA received comments by September 30, 1994, that illustrated that an extension of the compliance dates would not be in the public interest. RSPA received two comments opposed to and one comment in support of extending the compliance date for provisions applicable to RMW. The comment advocating the extension was submitted by the American Hospital Association (AHA). The AHA fully supported RSPA's decision to extend the compliance date for RMW and encouraged continued coordination with other Federal agencies involved in the regulation of infectious substances. The comments opposing the extension were submitted by a manufacturer of an exemption packaging used for transporting RMW and one of its customers, a waste transporter. Both commenters requested that the requirements for RMW be implemented without further delay. The manufacturer stated that it has spent in excess of \$2 million developing its packaging, and that large transporters of RMW have ``done little or nothing to help toward the safety of RMW transportation.'' The waste transporter stated that, by using the manufacturer's exemption packaging, it has an edge over many of the large transporters that are not and possibly may elect not to comply with the new requirements. The waste transporter stated that Federal regulations are necessary if safeguards are to be put in place for the safety and health of the public. Neither commenter provided any specific data or information suggesting that RMW is being transported unsafely, nor did they demonstrate that the extension would jeopardize safety or be contrary to the public interest. Based on these comments, and on the lack of any evidence indicating that a limited extension would adversely affect public health and safety, RSPA has determined that it is appropriate to extend the compliance dates. Therefore, RSPA is confirming the compliance dates set forth in the September 22, 1994 final rule.

Issued in Washington, DC on October 14, 1994, under authority delegated in 49 CFR part 106, appendix A.

Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety.

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